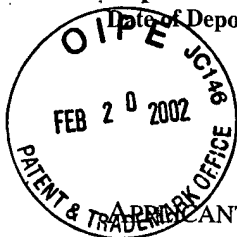


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Pravin Chaturvedi and Ene Ette
ASSIGNEE: Vertex Pharmaceuticals Incorporated
SERIAL NUMBER: 09/941,282
FILING DATE: August 28, 2001
EXAMINER: Not Yet Assigned
ART UNIT: Not Yet Assigned
FOR: Optimal Compositions and Methods Thereof for Treating HCV Infections

February 20, 2002
Cambridge, Massachusetts

Honorable Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith. The order of presentation of the references should not be construed as an indication of the importance of the references.

U.S. Patent Documents:

None

Foreign Patent Documents:

None

Other Prior Art – Non Patent Literature Documents:

1. Paul Glue, M.D., Ph.D., "The Clinical Pharmacology of Ribavirin", Seminars in Liver Disease, 19:[Suppl. 1] 17-24, 1999
2. Salin Khakoo et al., "Ribavirin and Interferon alfa-2b in Chronic Hepatitis C: Assessment of Possible Pharmacokinetic and Pharmacodynamic Interactions", Br. J. Clin. Pharmacol, 46: 563-570, 1998

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APPLICANTS: Chaturvedi et al.,
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3. M. Brunet et al., "Pharmacokinetics and Pharmacodynamics of Mycophenolic Acid in Stable Renal Transplant Recipients Treated with Low Doses of Mycophenolate Mofetil", *Transpl. Int.*, 13 [Suppl. 1] 13: S301-S305, 2000
4. John G. McHutchinson, M.D., et al., "Combination Therapy With Interferon Plus Ribavirin for the Initial Treatment of Chronic Hepatitis C", *Seminars in Liver Disease*, 19 [Suppl. 1]: 57-65, 1999

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the application;
- ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International Application; or
- ☒ before the mailing date of a first Office Action on the merits in the above-identified case.

Accordingly, no fee or certification is required. 37 C.F.R. §1.97.

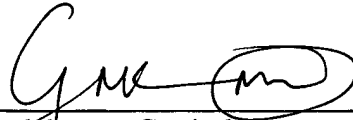
A copy of each of the above-identified publication is enclosed herewith. Applicants request the Examiner to consider completely the cited documents in determining the patentability of the present claims, and to sign the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

APPLICANTS: Chaturvedi et al.,
U.S.S.N.: 09/942,282

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0725, Reference No. VPI/01-119.

Respectfully submitted,



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Dated: February 20, 2002



**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
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LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

Nandakumar Govindaswamy is hereby given limited recognition under 37 CFR §10.9(b) as an employee of Vertex Pharmaceuticals, Inc. to prepare and prosecute patent applications wherein the patent application is assigned to Vertex Pharmaceuticals, Inc., and the attorney or agent of record in the applications is a registered practitioner who is an employee of Vertex Pharmaceuticals, Inc.

This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Nandakumar Govindaswamy ceases to lawfully reside in the United States, (ii) Nandakumar Govindaswamy's employment with Vertex Pharmaceuticals, Inc. ceases or is terminated, or (iii) Nandakumar Govindaswamy ceases to remain or reside in the United States on an H-1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Expires: March 1, 2002

Harry Moatz,
Director of Enrollment and Discipline